## Accreditation Process Committee Conference Call

3/16/00

Participants: Mary Ann Baumgart; Janet Cruse; Maureen Hamilton; Dave Hill; Bob Pulano; Gleason Wheatley; John Griggs, Chair

## Summary:

The first item discussed during the conference call was the revised language for section 4.0. Based on discussions from the previous conference call, revised language for section 4.0 was developed and distributed prior to the conference call. The revised language reads as follows:

## 4.0 Accreditation Process

Laboratories applying for accreditation may be fixed-base or mobile. In addition fixed-based and mobile laboratories may function as auxiliary laboratories to a parent laboratory. An auxiliary laboratory is any fixed-base or mobile facility operated by the owner of the parent laboratory to provide additional capacity or to respond to temporary situations.

- a) An individual fixed-base laboratory requires a separate accreditation. The primary accrediting authority shall determine what constitutes an individual fixed-base laboratory when noncontiguous auxiliary fixed-base laboratories operate under the same ownership, oversight and quality system as the parent laboratory.
- b) An auxiliary mobile laboratory is owned by an accredited fixed-base laboratory, operates under the same quality system as the fixed-based laboratory, and performs a subset of the analyses for which the fixed-base laboratory is accredited.
  - 1) For an auxiliary mobile laboratory that operates exclusively within the state in which the parent fixed-base laboratory is located, the primary accrediting authority shall determine if a separate accreditation is required.
  - 2) For an auxiliary mobile laboratory that operates outside of the state in which the parent fixed-base laboratory is located, a separate accreditation from the primary accrediting authority is required.
- c) A mobile laboratory that is owned by a fixed-base laboratory but operates under a different quality system or performs analyses for which the parent fixed-base laboratory is not accredited requires its own accreditation.

d) A mobile laboratory that is not owned and operated by a fixed-base laboratory requires its own accreditation.

The proposed language was discussed by the participants of the conference call. There was agreement among the committee members on the content and organization of section 4.0 The committee members agreed that the proposed section 4.0 should be put up for a vote at the annual meeting.

The next item discussed was some language developed by Janet Cruse on secondary application packages. The proposed language reads as follows:

A laboratory seeking accreditation from a secondary accrediting authority (ies) shall complete and submit a secondary application package. The secondary application package must include all information as in an application for accreditation (see Section 4.1.7 above) excluding the Quality Manual. The secondary application package shall include a copy of the most recent Certificate of Accreditation issued by the primary accrediting authority (ies) indicating the fields of testing (program, method, analyte). Refer to Section 4.2 for the assessment of fees (if applicable) and Section 4.4.1 (1) and (2) for the reasons to deny a secondary application package.

The proposed language was discussed and there was agreement among the committee members on the content. Janet Cruse suggested that the proposed language be added at the end of section 4.1.7. This was followed by some discussion on creating two subsections to 4.1.7 - one dealing with the primary application package and another dealing with the secondary application package. After some discussion, there was agreement among the conference call participants on dividing section 4.1.7 into two sections.

The next item discussed was ELAB's recommendation that the Accreditation Process Committee develop an advisory appendix on the issue of due process for laboratories. After some discussion, it was decided that the best approach would be to develop a short section on due process for inclusion at the end of the chapter and discuss it further at the annual meeting. John Griggs indicated that he would send out a selection form to the committee members to schedule the next conference call.